

OCT 24 2001

K012792
510(k) SUMMARY

Submitter's Name: Warepalmy Enterprise LLC (USA)
1725 NE Orenco Station Parkway
Hillsboro, OR 97124
(503) 693-6516

Date summary prepared: August 17, 2001

Device name:

Proprietary name: C.T.M. Mobility Scooter HS-360
Common or usual name: Electric scooter.
Classification name: Motorized three-wheeled vehicle, Class II,
21 CFR 890.3800.

Legally marketed device for substantial equivalence comparison:

Sunrunner TE-777-4 submitted by Pride Health Care, Inc. and cleared for marketing under 510(k) #K923193.

Description of the device:

The C.T.M. Mobility Scooter HS-360 is an indoor/outdoor electric scooter that is battery operated. It has a base with four wheels with adjustable padded seats, armrests and headrests. The movement of the scooter is controlled by the rider who uses hand controls located at the top of the steering column. This modes can be disassembled for transport and is provided with a battery charger.

Intended use of device:

The device is an indoor/outdoor scooter that provides transportation for disabled or elderly persons.

Technological characteristics:

The device features and use parameters of the C.T.M. Mobility Scooter and the Sunrunner TE-777-4 are very similar. Both are indoor/outdoor electric scooters that are battery operated and have automatic braking systems. Batteries and battery chargers are provided with each scooter. Use parameters are very similar, varying only slightly with selected parameters, such as with the maximum distance that each scooter can be driven.

Testing conducted:

Tests listed in the *Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three Wheeled Vehicles*, July 1995, were conducted and the results included in the subject 510(k) submission.

Performance testing:

Comparative performance testing and clinical evaluations were not submitted as part of this 510(k).



OCT 24 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Warepalmy Enterprise LLC (USA)
c/o Mr. Robert S. McQuate
R.S. McQuate & Associates
3636 E. Columbine Drive
Phoenix, Arizona 85032

Re: K012792
Trade/Device Name: C.T.M. Mobility Scooter HS-360
Regulation Number: 890.3800
Regulation Name: motorized three wheeled vehicle
Regulatory Class: II
Product Code: INI
Dated: October 3, 2001
Received: October 5, 2001

Dear Mr. McQuate:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

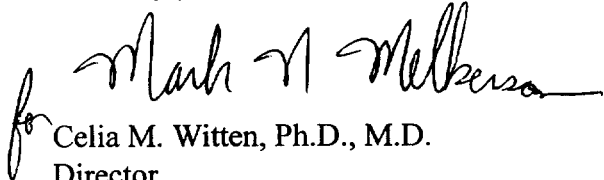
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


for Celia M. Witten, Ph.D., M.D.

Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K012792

Device name: C.T.M. Mobility Scooter HS-360

Indications for Use:

The C.T.M. Mobility Scooter HS-360 is an indoor/outdoor scooter that provides transportation for disabled or elderly persons.

(Please do not write below this line)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Melhous

(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

510(k) Number K012792

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☒

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